K090552

MAR 16 2009

Attachment 1

Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Trade Name:	UroCARE1.0
CFR Section:	21 CFR Part 892.2050
Classification Name:	Picture Archiving and Communication System (PACS).
Product Code:	LLZ
Device Class:	Class II
Applicable Standard:	DICOM 3.0
Manufacturer and Distributor:	Neusoft Medical Systems Co., Ltd. No.3-11,Wenhua Road, Heping District, Shenyang, China Post Code : 110004
Submitter:	Contact : Tian Yanfang Title : Manager of Quality Management Department Tel : 86-24-83660649 Fax : 86-24-83780480 E-Mail : Tianyanfang@neusoft.com Summary prepared : Nov.18,2008

Safety and Effectiveness Information

Intended Uses:

The UroCARE1.0 is a soft-copy reading workstation intended for clinical review of CT abdominal (urology) images which allows easy acquisition, transmission and review of the medical images and supports HD ROI (High Density Region of Interest) analysis. Images may be interpreted by a trained physician to obtain information that may be useful in the determination of a diagnosis, except in the case of mammography images.

Device Description:

UroCARE1.0 software product is a soft-copy reading workstation for clinical review of CT abdominal (urology) images. It is a self-contained software package and provides general features of 2D image display, standard Multi-Planar Reformation (MPR) views and 3D views of Volume Rendering. An additional feature, HD ROI analysis, allows for segmentation of high density regions in terms of user-defined threshold within a user-given ROI as well as display and quantitative analysis of the segmented HD ROI.

Predicate Device:

K052995 : Advantage Workstation 4.3
K041521 : Volume Viewer Plus

Statement of Substantial Equivalence:

The Neusoft UroCARE1.0 is comparable and substantially equivalent to the Advantage Workstation 4.3 (K052995) and the Volume Viewer Plus Aquarius Workstation (K0141521).

The UroCARE1.0 and the Advantage Workstation 4.3 share similar technological specifications. Both of them support DICOM protocol for communication of images with other medical imaging devices. Furthermore, they both provide various tools for physicians to view images.

The UroCARE1.0 has the similar technological characteristics with the Volume Viewer Plus. Both of them provide functions such as standard MPR, 3D display of volume rendering, and they both provide the function of ROI segmentation by user -defined threshold, as well as display and quantitative analysis of the ROI and quantitative analysis.

According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neusoft Medical Systems Co., Ltd.
% Mr. Daniel W. Lehtonen
Technical Reviewer
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

MAR 1 6 2009

Re: K090552
Trade/Device Name: UroCARE1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 26, 2009
Received: March 2, 2009

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number: K090552

Device Name: UroCARE1.0

The UroCARE1.0 is a soft-copy reading workstation intended for clinical review of CT abdominal (urology) images which allows easy acquisition, transmission and review of the medical images and supports HD ROI (High Density Region of Interest) analysis. Images may be interpreted by a trained physician to obtain information that may be useful in the determination of a diagnosis, except in the case of mammography images.

Prescription Use YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090552